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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,517	07/03/2003	Dirk Boecker	38187-2688.US	4774

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Goodwin Procter LLP
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EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
01/26/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/613,517	BOECKER ET AL.	
	Examiner	Art Unit	
	JEFFREY G. HOEKSTRA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,13-17,21,24,27,57 and 65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,13-17,21,24,27,57 and 65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 May 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date : 9/23/2009, 12/08/2009, and 01/15/2010.

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 10/23/2009, amendment(s) to the specification, amended claim(s) 1, 13, 21, 24, 27, 57, and 65, and canceled claim(s) 52, 54, and 57 is/are acknowledged. The previous rejections of the claims is/are *withdrawn*. The following new and/or reiterated ground(s) of rejection is/are set forth:

Information Disclosure Statement

2. The information disclosure statement(s) (IDS) submitted on 9/23/09, 12/08/09, and 1/15/10 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

3. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b).** Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Objections

4. Claim 27 is objected to because of the following informalities: the positive recitation of "wherein the processor is utilized to monitor position and speed of the

active one of said penetrating members as the active one of said penetrating members moves in the first direction toward a target tissue, wherein the application of a launching force to the penetrating member is controlled based on position and speed of the penetrating member" should apparently read "wherein the processor is utilized to monitor position and speed of the active one of said penetrating members as the active one of said penetrating members moves in a first direction toward the tissue site, wherein an application of a launching force to the active one of said penetrating members is controlled based on a position and a speed of the active one of said penetrating members", or the like. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 65 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The scope of claim 65 is indeterminate because of the two separate positive recitations of ""a processor coupled to the penetrating member driving configured to provide instructions for a fast-into of penetrating members into a tissue site and slow-out velocity out of the tissue site". The scope of the claim appears to include two processors performing identical functions. It does not appear Applicant intended to

include the second recitation and it appears to be a typographical error; however, the scope of the claims remains indefinite.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 13-17, 21, 24, 27, 57, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levaughn et al. (US 7,150,722 B2, hereinafter Levaughn) in view of Cunningham et al. (6,306,104 B1, hereinafter Cunningham).

11. For claim 1, Levaughn discloses and shows a body fluid sampling system (2) for use on a tissue site (Abstract), the system comprising *inter alia*:

- a disposable (50) (as best seen in Figure 4) (column 14 line 9 – column 16 line 57);

- a penetrating member driver (44) (as best seen in Figure 3) (column 14 line 9 – column 16 line 57);
- a plurality of penetrating members (8) (as best seen in Figures 3-4) (column 14 line 9 – column 16 line 57) arranged in a radial configuration in the disposable (as best seen in Figure 4) (column 14 line 9 – column 16 line 57), wherein sharpened distal tips of the penetrating members point radially outward (as best seen in Figure 4) (column 14 line 9 – column 16 line 57), wherein an active one of said penetrating members may be operatively coupled to said penetrating member driver (column 14 line 9 – column 16 line 57), said penetrating member driver moving said active one along a path out of a housing having a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site (column 14 line 9 – column 16 line 57); and
- a plurality of analyte detecting members (10) (as best seen in Figure 4) (column 14 line 9 – column 16 line 57) positioned in the disposable (as best seen in Figure 4), wherein at least one of said analyte detecting members is positioned to receive fluid from a wound created by said active one of said penetrating members (as best seen in Figure 1) (column 14 line 9 – column 16 line 57), wherein said detecting members are not pierced by the active one of the penetrating members (as best seen in Figure 4) (column 14 line 9 – column 16 line 57).

12. For claim 21, Levaughn discloses and shows a body fluid sampling system, wherein the penetrating member driver is a motor and gear box (column 14 line 9 – column 16 line 57).

13. For claim 57, Levaughn discloses and shows a body fluid sampling system, wherein each of the plurality of penetrating members is an elongate member without molded attachments (as best seen in Figure 4) (column 14 line 9 – column 16 line 57).

14. For claim 65, Levaughn discloses and shows a body fluid sampling system (2) for use on a tissue site (Abstract), the system comprising *inter alia*:

- a disposable (50) (as best seen in Figure 4) (column 14 line 9 – column 16 line 57);
- a penetrating member driver (44) (as best seen in Figure 3) (column 14 line 9 – column 16 line 57);
- a plurality of penetrating members (8) (as best seen in Figure 4) (column 14 line 9 – column 16 line 57) arranged in a radial configuration in the disposable (as best seen in Figure 4) (column 14 line 9 – column 16 line 57), wherein sharpened distal tips of the penetrating members point radially outward (as best seen in Figure 4) (column 14 line 9 – column 16 line 57), wherein an active one of said penetrating members may be operatively coupled to said penetrating member driver (column 14 line 9 – column 16 line 57), said penetrating member driver moving said active one along a path out of a housing having a penetrating member exit, into said tissue site, stopping in said tissue site, and withdrawing out of said tissue site (column 14 line 9 – column 16 line 57);
- a plurality of analyte detecting members (10) (as best seen in Figure 4) (column 14 line 9 – column 16 line 57) positioned in the disposable (as best seen in Figure 4), wherein at least one of said analyte detecting members is positioned to receive fluid from a wound created by said active one of said penetrating members (as best seen

in Figure 4) (column 14 line 9 – column 16 line 57), wherein said detecting members are not pierced by the active one of the penetrating members (as best seen in Figure 1) (column 14 line 9 – column 16 line 57); and

- a coupler (48) (as best seen in Figure 3) (column 14 line 9 – column 16 line 57) on said penetrating member driver configured to engage at least a portion of said elongate portion of the penetrating member and drive said member along a path into the tissue site and withdrawn from the tissue site (as best seen in Figure 3) (column 14 line 9 – column 16 line 57).

15. For claims 1, 13-17, 21, 24, 27, 57, and 65, Levaughn discloses the claimed invention as set forth and cited above except for expressly disclosing the following:

- for claims 1 and 65, a processor coupled to the penetrating member driving configured to provide instructions for a fast-into of penetrating members into a tissue site and slow-out velocity out of the tissue site;
- for claim 13, a body fluid sampling system, further comprising a penetrating member sensor positioned to monitor the active one of said penetrating members coupled to said penetrating member driver, the penetrating member sensor configured to provide information relative to a depth of penetration of a penetrating member through a skin surface;
- for claim 14, a body fluid sampling system, wherein the depth of penetration is about 100 to 2500 microns;

- for claim 15, a body fluid sampling system, wherein the depth of penetration is 500 to 750 microns;
- for claim 16, a body fluid sampling system, wherein the depth of penetration is no more than about 1000 microns beyond a stratum corneum thickness of a skin surface;
- for claim 17, a body fluid sampling system, wherein the depth of penetration is no more than about 500 microns beyond a stratum corneum thickness of a skin surface;
- for claim 24, a body fluid sampling system, wherein the processor is utilized to monitor position and speed of the active one of said penetrating members as the active one of said penetrating members moves in a first direction; and
- for claim 27, a body fluid sampling system, wherein the processor is utilized to monitor position and speed of the active one of said penetrating members as the active one of said penetrating members moves in a first direction toward the tissue site, wherein an application of a launching force to the active one of said penetrating members is controlled based on a position and a speed of the active one of said penetrating members.

16. Cunningham teaches a body fluid sampling system, comprising *inter alia*:

- for claims 1 and 65, a processor (column 13 lines 33-67) coupled to a penetrating member (67) (column 9 line 40 – column and column 12 line 40 and column 13 lines 33-34) driving configured to provide instructions (column 13 lines 33-67) for a fast-into of an active one of the penetrating members into a tissue site and slow-out velocity out of the tissue site (the Examiner notes the microprocessor automatically

initiates and controls the high pressure piston based lancet insertion into the tissue site and subsequently the spring based lancet retraction; the automated insertion velocity is greater than the retraction velocity) (column 9 line 40 – column and column 12 line 40 and column 13 lines 33-34);

- for claim 13, a body fluid sampling system, further comprising a penetrating member sensor (column 13 lines 33-64) positioned to monitor an active one of said penetrating members coupled to said penetrating member driver (38) (column 9 lines 42-44), the penetrating member sensor configured to provide information relative to a depth of penetration of a penetrating member through a skin surface (column 13 lines 33-64);
- for claim 14, a body fluid sampling system, wherein the depth of penetration is about 100 to 2500 microns (column 9 lines 29-44);
- for claim 15, a body fluid sampling system, wherein the depth of penetration is 500 to 750 microns (column 9 lines 29-44);
- for claim 16, a body fluid sampling system, wherein the depth of penetration is capable of being no more than about 1000 microns beyond a stratum corneum thickness of a skin surface (column 9 lines 29-44);
- for claim 17, a body fluid sampling system, wherein the depth of penetration is capable of being no more than about 500 microns beyond a stratum corneum thickness of a skin surface (column 9 lines 29-44);
- for claim 24, a body fluid sampling system, wherein the processor (column 13 lines 33-34) is inherently capable of monitoring position and speed of the active one of

said penetrating members as the active one of said penetrating members moves in a first direction (column 13 lines 33-34); and

- for claim 27, a body fluid sampling system, wherein the processor (column 13 lines 33-34) is inherently capable of being utilized to monitor position and speed of the active one of said penetrating members as the active one of said penetrating members moves in a first direction toward the tissue site (column 13 lines 33-34), wherein an application of a launching force to the active one of said penetrating members is capable of being controlled based on a position and a speed of the active one of said penetrating members (column 13 lines 33-34)

17. All the claimed body fluid sampling system elements were known in the prior art and one skilled in the art could have combined the body fluid sampling system elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the body fluid sampling system component parts are known in Levaughn and Cunningham. The only difference is the combination of the body fluid sampling system component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the body fluid sampling system components as taught by Levaughn with the body fluid sampling system components as taught by Cunningham to achieve the predictable results of monitoring and controlling a penetration depth, position and speed of a lancet using a processor in order to decrease perceived pain by the lancing subject.

Response to Arguments

18. Applicant's arguments filed 10/23/2009 have been fully considered but they are not persuasive.

19. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

20. Applicant's arguments (see page 7 filed 10/23/2009) merely paraphrase the claimed invention and generally state "None of the references, either singularly or in combination, teach a body fluid sampling system that includes, (i) penetrating members and analyte detecting members positioned in a disposable, (ii) a processor coupled to a penetrating member driving configured to provide instructions for a fast-into a tissue site and slow-out velocity out of the tissue site and (iii) detecting members not pierced by penetrating members".

21. Although the arguments appear to fail to comply with 37 CFR 1.111(b), but since the rejection is based upon previously applied prior art, the Examiner notes in response the following:

22. In response to (i), Levaughn clearly discloses and shows penetrating members (8) and analyte detecting members(10) positioned in a disposable (50) (see Figures 3-4) (column 14 line 9 – column 16 line 57).

23. In response to (ii), Cunningham teaches using a processor (column 13 lines 33-67) coupled to a penetrating member (67) (column 9 line 40 – column and column 12

line 40 and column 13 lines 33-34) driving configured to provide instructions (column 13 lines 33-67) for a fast-into of an active one of the penetrating members into a tissue site and slow-out velocity out of the tissue site. The Examiner notes the microprocessor automatically initiates and controls the high pressure piston based lancet insertion into the tissue site and subsequently the spring based lancet retraction. The automated insertion velocity must be greater than the retraction velocity (column 9 line 40 – column and column 12 line 40 and column 13 lines 33-34) because during insertion the high pressure piston-based driver must overcome the force applied by the spring.

24. In response to (iii), Levaughn clearly discloses and shows analyte detecting members not pierced by penetrating members (see Figures 3-4) (column 14 line 9 – column 16 line 57).

Conclusion

25. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736